REMARKS

Upon entry of this amendment, claims 1, 3, 5-16, 36-51, and 60-61 are pending. Claims 2, 4, 17-35, and 52-59 are canceled and claims 60-61 are new. Claims 1, 15, and 36-44 are amended.

35 U.S.C. § 112 Rejection

Reconsideration of the rejection of claims 1, 12-16, 36-38, and 40-44 under the enablement requirement of 35 U.S.C. § 112 is requested. The Examiner asserts that the specification does not "reasonably provide enablement for any acid resin to any animal with any disease."[1] However, without conceding the propriety of the rejection and in order to advance prosecution, claim 1 has been amended to require that the animal subject is suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload. Thus, the claim is limited to animals suffering from specific diseases and a skilled person would have been able to test the acid resins for effectiveness against these specific diseases using only routine experimentation. Thus, claim 1, and the claims that depend therefrom are enabled under 35 U.S.C. § 112.

Further, the Examiner states that "[t]he said resin is described as loaded with NH_4, H or K. There is no other description of this species ...."[2] However, the Examiner fails to take into consideration the discussion regarding sodium-binding polymers in the specification at paragraphs [0041] to [0046]. Several specific sodium-binding polymers are described in this section of the application. This description along with the discussion of treatment of ion imbalances and fluid overload in paragraphs [0072] to [0078] and the examples would have provided a person of ordinary skill with the guidance needed to make the sodium-binding polymers and use the claimed methods. Further, the M.P.E.P. states that "[c]ompliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn on whether an example is disclosed," nor must the specification include a working example for each and every embodiment of a claimed invention.[3] Examples can be prophetic or even non-existent altogether. Thus, the Office cannot reject the claims for lack of enablement simply because the

[1] See Office action dated June 5, 2007 at page 2.
[2] See id.
[3] M.P.E.P. § 2164.02; In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

applicants' examples are prophetic. Applicants' have provided enough direction in the specification and examples to allow a person of ordinary skill to use the claimed methods without undue experimentation. In sum, claim 1, and the claims that depend therefrom are enabled under 35 U.S.C. § 112.

35 U.S.C. § 102 Rejection

Reconsideration is requested of the rejection of claims 1 and 12 as anticipated by U.S. Patent No. 5,935,599 (Dadey) under 35 U.S.C. § 102(b). The Office asserts that the instant resins are administered to patients with nephropathology.[4] However, Dadey describes polymer-associated liposomes (PALs) wherein an anionic polymer is intertwined through the bilayer structure of the liposome, so the anionic polymer is present on the external and internal surfaces of the liposome. These PALs are used as drug delivery systems, particularly to deliver insulin. The anionic polymer in the PAL is then used to complex a positively charged site on the drug to be delivered. These PAL-drug complexes are absorbed into the subject's system and can be tailored to target particular tissues. In contrast, the sodium-binding compositions of claim 1 and acid resins of claim 12 are non-absorbed and remain in the gastrointestinal tract where the compositions bind sodium and remove it from the subject's body when the compositions are excreted in the feces. Thus, claims 1 and 12 are not anticipated by U.S. Patent No. 5,935,599 (Dadey) under 35 U.S.C. § 102(b).

35 U.S.C. § 103 Rejection

Reconsideration is requested of the rejection of claims 1 and 12 as obvious in view of U.S. Patent No. 5,935,599 (Dadey) under 35 U.S.C. § 103. The Dadey reference is described in more detail in connection with the § 102(b) rejection. In contrast to the PAL-drug complexes described by Dadey, the sodium-binding compositions of claim 1 and acid resins of claim 12 are non-absorbed and remain in the gastrointestinal tract where the compositions bind sodium and remove it from the subject's body. Thus, a person skilled in the art would not have contemplated the sodium-binding compositions of claims 1 and 12 from a reading of the Dadey reference.

[4] See Office action dated June 5, 2007 at page 3.

Accordingly, claims 1 and 12 are not obvious in view of U.S. Patent No. 5,935,599 (Dadey) under 35 U.S.C. § 103.

Provisional Double Patenting Rejection

Reconsideration is requested of the provisional rejection of claims 1, 12, and 13-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 5, 8-17, and 30 of copending Application No. 10/965,274. It is noted that the claims of the '274 application have been amended. The only independent claim pending in the '274 application is claim 43. Claim 43 is directed to methods of treating hyperkalemia in an animal subject comprising (i) administering to said animal subject an effective amount of a potassium-binding, cation-exchange polymer, the cation-exchange polymer being orally administered in a form having a combination of counterions selected from Ca^{2+}, H^{+}, NH_4^{+}, and Na^{+}, and (ii) binding and removing potassium from a gastrointestinal tract of said animal subject with said polymer.

The analysis employed in an obvious-type double patenting rejection parallels the guidelines of a 35 U.S.C. § 103 obviousness determination.[5] However, an important distinction exists. A rejection for obviousness must be based on a comparison of the claimed invention to the entirety of the disclosure in the prior art reference, whereas an obviousness-type double patenting rejection must be grounded on a comparison of the claimed invention to the claims, **and only the claims**, of the reference.[6]

It is respectfully submitted that the subject matter of the claims of the present application would not have been obvious in view of the claims of copending Application No. 10/965,274. When evaluating the scope of a claim, every element of the claim must be considered.[7] To support an obviousness-type double patenting rejection, the claims must have been obvious at the time of filing and not merely obvious upon hindsight reconstruction using applicant's disclosure as a template to arrive at the features of the instantly claimed methods from the claims of the '274 application. It is respectfully submitted that the Office has failed to establish obviousness

[5] In re Braat, 937 F.2d 589 (Fed. Cir. 1991).
[6] Purdue Pharma L.P. v. Boehringer Ingelheim GMbH, 98 F.Supp.2d 362, 392, 55 USPQ2d 1168, 1190 (S.D.N.Y. 2000), *aff'd*, 237 F.3d 1359, 57 USPQ2d 1647 (Fed. Cir. 2001).
[7] See, e.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

based on any reference or by evidence of the level of skill in the art or the nature of the problem that is not based upon impermissible hindsight reconstruction.

Subject claim 1 is directed to methods of removing sodium by administering an effective amount of a non-absorbed sodium-binding polymer having an *in vivo* sodium binding capacity of 4 mmol or more per gram of polymer in a human. This method is used to treat animal subjects suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload. In contrast, claim 43 of the '274 application is directed to methods of treating hyperkalemia by administering a potassium-binding, cation-exchange polymer and removing potassium from the gastrointestinal tract. Claim 43 for the '274 application does not include the elements of (1) removing sodium from an animal subject, (2) a sodium-binding polymer having an *in vivo* sodium binding capacity of 4 mmol or more per gram of polymer in a human, or (3) treating animal subjects suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload. Thus, claim 43 of the '274 application does not include all the elements of the subject claims 1, 12, and 13-44, and therefore, the subject claims are not obvious in view of the claims of the '274 application.

CONCLUSION

Applicant submits that the present application is now in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge the fee for a two-month extension of time in the amount of $460.00 to Deposit Account No. 19-1345. The Commissioner is also hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,

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JSH/clp